4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0790]

Breckenridge Pharmaceutical, Inc.; Withdrawal of Approval of Abbreviated New Drug Application for Solifenacin Succinate Tablets, 5 Milligrams and 10 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the abbreviated new drug application (ANDA) for solifenacin succinate tablets, 5 milligrams (mg) and 10 mg, held by Breckenridge Pharmaceutical, Inc., 15 Massirio Dr., Berlin, CT 06037 (Breckenridge). Breckenridge requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On May 20, 2019, FDA approved ANDA 209818 for solifenacin succinate tablets, 5 mg and 10 mg, for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. On January 23, 2020, Breckenridge issued a field alert report that solifenacin succinate tablets, 5 mg and 10 mg, may convert to solifenacin tartrate tablets during manufacturing due to an interaction between solifenacin succinate and tartartic acid, which is an inactive ingredient in this drug product's formulation. On January 24, 2020, Breckenridge executed a Class II Recall (Retail-Level) of all solifenacin succinate tablet product lots that were distributed to market. Breckenridge cannot

market its solifenacin succinate tablet product under the current approval conditions for ANDA 209818. To the extent that its active ingredient has converted from solifenacin succinate to solifenacin tartrate, the product Breckenridge has distributed under ANDA 209818 is misbranded.

After discussions with FDA, on April 21, 2020, Breckenridge requested that FDA withdraw approval of ANDA 209818 for solifenacin succinate tablets under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 209818 solifenacin succinate tablets, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of solifenacin succinate tablets into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: August 17, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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